



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Wolfgang HEIL et al. Confirmation No.: 7991  
Serial No.: 09/757,688 Examiner: L.S. Channavajjala  
Filed: January 11, 2001 Group Art Unit: 1615  
Title: DROSPIRENONE FOR HORMONE REPLACEMENT THERAPY

**INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. §§ 1.56, 1.97 AND 1.98**

MAIL STOP FEE AMENDMENT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This information disclosure statement is made in accordance with 37 C.F.R. §§ 1.56, 1.97 and 1.98 as follows:

**TIMING AND FEES**

- Under 37 C.F.R. § 1.97(b), no fee or statement is required for filing this information disclosure statement is filed:
  - within three months of the filing date of a national application other than a CPA under § 1.53(d);
  - within three months of the actual filing date of the national phase of a PCT application; OR
  - before the mailing of a first substantive office action (including after filing of an RCE).
- Under 37 C.F.R. § 1.97(c), this information disclosure statement is filed after the periods specified in 37 C.F.R. § 1.97(b), but before the mailing date of:
  - a final rejection under 37 C.F.R. § 1.113;
  - termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P. § 609(B)(2); OR
  - a notice of allowance under 37 C.F.R. § 1.311; and

is accompanied by:

- the statement as specified in 37 C.F.R. § 1.97(e) set out below; OR
- a check covering the fee of \$180.00 under 37 C.F.R. § 1.17(p).

Under 37 C.F.R. § 1.97(d), this information disclosure statement is filed after the mailing date of the following actions which have not been withdrawn:

- a final action under 37 C.F.R. § 1.113;
- termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P. § 609(B)(2); OR
- a notice of allowance under 37 C.F.R. § 1.311;

AND is filed on or before payment of the issue fee; AND is accompanied by:

- the statement as specified in 37 C.F.R. § 1.97(e) as set forth below, and the fee of \$180.00 under 37 C.F.R. § 1.17(p).

#### **STATEMENTS UNDER 37 C.F.R. 1.97(e)**

- Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application having a mailing date not more than three months prior to the filing date of this information disclosure statement; or
- No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned attorney after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing date of the information disclosure statement.

#### **CITED MATERIALS**

- Copies of materials listed but not attached were cited in benefit (35 U.S.C. § 120) ancestor application Serial No. \_\_\_\_\_, on Form 892 by the Examiner and/or Form 1449 by the applicant; see 37 C.F.R. § 1.98(d).
- Copies of materials listed but not attached were cited in an international search report dated \_\_\_\_\_.
- Copies of the materials listed are attached (except for the foregoing).

#### **NON-ENGLISH LANGUAGE REFERENCES**

- An English-language search report or equivalent paper from a foreign patent office is provided indicating the relevance of the cited reference(s).
- A foreign-language search report from a foreign patent office is provided, and pertinent parts are translated substantively below:

X = document of particular relevance when it is taken alone  
Y = document of particular relevance when it is combined with another such document  
A = document defining the general state of the art  
O = non-written disclosure  
P = intercalated document  
T = document cited to understand the theory or principle underlying the invention  
E = patent document which has the benefit of a date earlier than the filing date and which was published only on or after this filing date  
D = cited in the application  
L = cited for another reason  
& = publication of member of same patent family

Translation of other relevant information on foreign search report

**OTHER INFORMATION**

None

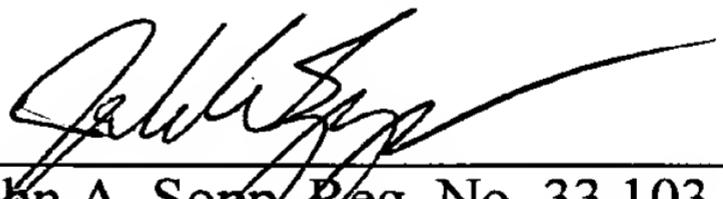
**PAYMENT OF FEES DUE (IF ANY):**

A check for \$ covering the fee identified above is attached.

Please charge to Deposit Account No. 13-3402 \$ \_\_\_\_\_ for the fee identified above.

The Commissioner is hereby authorized to charge or credit any overpayment to Deposit Account No. 13-3402, two copies of this paper are attached for this purpose.

Respectfully submitted,

  
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Date: March 7, 2005

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet

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of

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### Complete if Known

Application Number	09/757,688
Filing Date	January 11, 2001
First Named Inventor	Wolfgang HEIL et al.
Group Art Unit	1615
Examiner Name	L.S. Channavajjala

Attorney Docket Number

PLOVIN-2A

### U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code <sup>2</sup> (if known)		
		5,534,270		De Castro	7/9/1996

### FOREIGN PATENT DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
		CA	2 188 907			4/29/1997		

### NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		International Preliminary Examination Report dated 11/29/2001	
		Remington 2, Farmacia, 17 edicion, Editorial Medica, Panamericana	
		S. Budavari, et al., "The Merck Index", Merck & Co., Inc., Whitehouse Station, NJ (1996)	
		P. Giunchedi et al., "Spray-drying as a preparation method of microparticulate drug delivery systems: an overview, "STP Pharma Sciences 5 (4) 276-290 (1995)	
		J. Broadhead, et al., "The Spray Drying of Pharmactuticals", Drug Development and Industrial Pharmacy, 18 (11&12), pgs. 1169-1206 (1992)	
		P. Muhn et al., "Drospirenone: A Novel Progestogen with Antimineralocorticoid and Antiandrogenic Activity", Pharmacological Characterization IN animal Models (1995), pgs. 99-110	
		"Letters to the Editor", Gynecol Endocrinol 200, 14:476-478	
		J.W. Tack, "Invitation To the Doctoral Candidates' Colloquium", dated 2-5-1998	
		N. Sattar, et al., "Reproductive Endocrinology Lipoprotein Subfraction Changes in Normal Pregnancy: Threshold Effect of Plasma Triglyceride on Appearance of Small, Dense Low Density Lipoprotein", "The Journal of Clinical Endocrinology & Metabolism Vol. 82, No. 8 2483-2491 (1997)	
		Letter dated 7-7-2004 re: CHLE Patent Appln. No. 2353-20000 filed 8-30-2000	
		Opposition to a European Patent Office, Patent No. 1 214 076	
		CA 136:172763, "Method for preparing an oral formulation containing acid-sensitive drugs, Hsiao, et al.	
		CA 129:235662, "Stabilization of acid sensitive benzimidaxoles with amino acid/cyclodextrin combinations", Klokkers, et al.	
Examiner Signature		Date Considered	

<sup>1</sup> EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>2</sup> Unique citation designation number. <sup>3</sup> See attached Kinds of U.S. Patent Documents. <sup>4</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>5</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>6</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>7</sup> Applicant is to place a check mark here if English language Translation is attached.